4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 320

[Docket No. FDA-2016-N-0011]

Investigational New Drug Applications for Biological Products; Bioequivalence Regulations; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending its regulations to update the address for applicants to submit investigational new drug applications (INDs) for biological products regulated by the Center for Drug Evaluation and Research (CDER). FDA is also amending its regulations on the criteria and evidence to assess actual and potential bioequivalence problems (bioequivalence regulations) to correct a typographical error. FDA is taking this action to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6248, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: FDA is amending 21 CFR 312.140(a)(2) to update the address for applicants to submit INDs for biological products regulated by CDER. FDA is amending 21 CFR 320.33(f)(3) of its bioequivalence regulations to correct a typographical error

by removing the phrase "(first-class metabolism)" and adding in its place "(first-pass metabolism)."

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to update the address for the submission of INDs regulated by CDER and to correct a typographical error in the Agency's bioequivalence regulations.

List of Subjects

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312 and 320 are amended as follows:

PART 312--INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

§ 312.140 [Amended]

2. Section 312.140 is amended in paragraph (a)(2) by removing "CDER Therapeutic Biological Products" and adding in its place "Central", and by removing "12229 Wilkins Ave.,

Rockville, MD 20852" and adding in its place "5901-B Ammendale Rd., Beltsville, MD 20705-1266".

PART 320--BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

3. The authority citation for 21 CFR part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.

§ 320.33 [Amended]

4. Section 320.33 is amended in paragraph (f)(3) by removing "(first-class metabolism)" and adding in its place "(first-pass metabolism)".

Dated: March 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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